

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 930055-2035			
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		<p>Application Number 10/549,590</p> <p>First Named Inventor SATO et al.</p> <p>Art Unit 1615</p>	<p>Filed 20 September 2005</p> <p>Examiner HELM, Caralynne E.</p>		
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%; border: none;"><tr><td style="width: 50%; vertical-align: top;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input type="checkbox"/> attorney or agent of record. Registration number _____</p><p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>48,104</u></p></td><td style="width: 50%; vertical-align: top; padding-left: 20px;"><p><u>Howard C. Lee</u> Signature</p><p><u>/Howard C. Lee/</u> Typed or printed name</p><p><u>(202) 292-1539</u> Telephone number</p><p><u>19 May 2010</u> Date</p></td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input type="checkbox"/> attorney or agent of record. Registration number _____</p> <p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>48,104</u></p>	<p><u>Howard C. Lee</u> Signature</p> <p><u>/Howard C. Lee/</u> Typed or printed name</p> <p><u>(202) 292-1539</u> Telephone number</p> <p><u>19 May 2010</u> Date</p>
<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input type="checkbox"/> attorney or agent of record. Registration number _____</p> <p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>48,104</u></p>	<p><u>Howard C. Lee</u> Signature</p> <p><u>/Howard C. Lee/</u> Typed or printed name</p> <p><u>(202) 292-1539</u> Telephone number</p> <p><u>19 May 2010</u> Date</p>				
<p><input type="checkbox"/> *Total of _____ forms are submitted.</p>					

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

I. Status of claims

Claims 1, 3, 5, 6, 11, 12, 14-16 and 18 are pending in this application. There are no amendments after final to be considered (Note: Presuming the remaining claims are held in condition for allowance, the applicants provide authorization for the Examiner to cancel claim 14 by Examiner's Amendment). The applicants request reconsideration of the 35 U.S.C. 103(a) rejections made in the final rejection of 19 February 2010.

II. Basis for clear error in 35 U.S.C. 102(b) rejection

(In the interest of brevity, the applicants have combined the two "Uno" rejections and the two "Sulc" rejections)

A. "UNO" rejections – Consideration as a whole means the entire reference not just isolated elements from within the reference

Claims 1, 3-5 and 14-16 were rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Uno et al. ("Uno") in view of Aiache et al. ("Aiche"), Nishihara et al. (U.S. Pat. Appl. Pub. 2002-0164379 – "Nishihara"), Yasuda et al. (U.S. Patent 6,310,116 – "Yasuda") and Janda et al. ("Janda") and Ohmura et al. ("Ohmura").

When making a determination of obviousness, the references, Uno, Aiache, Nishihara, Yasuda and Janda and the applicants' claimed invention must be considered as a whole. It is well known that *"[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."* *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965)(emphasis added).

Moreover, the determination of whether the applicants' claimed invention is obvious is not a determination as to whether each individual element is obvious, but rather whether one of ordinary skill in the art would have found the simultaneous combination of the claimed elements to have been obvious.

While there is no limitation on the number of references which can be used to support an obviousness rejection, the very fact that six (6) references were needed to establish obviousness

for a claim without an extraordinary number of elements is an indicia that the claimed invention would not have been obvious to one of ordinary skill in the art.

In addition, when considering the totality of the possible solutions represented by the combination of Uno, Aiache, Nishihara, Yasuda, Janda and Ohmura, one of ordinary skill in the art would not be confronted with a finite number of identifiable predictable solution or predictable results.

It is noted that Uno does not teach or suggest inclusion of compounds such as MAPTAC in view of the effects achieved by the monomer having a nitrogen atom in its side chain such as (meth)acrylamide (i.e. the drug delivery ophthalmic lens of the present invention has excellent strength with less change in size as well as having high inclusion and sustainable release of a drug (see page 5, fourth paragraph of applicants' specification).

In contrast, Ohmura does not show high inclusion or sustainable release of the cationic group-containing which is unsurprising as it is generally directed to modifying the surface of polymer materials and contains no teaching regarding ophthalmic lenses. As such, one of ordinary skill in the art would not have found the particular element of a monomer having a nitrogen atom in its side chain being (meth)acrylamide to be an obvious element to be selected as Ohmura (or any other of the cited references) lends no direction to such a selection or even to a selection of this element to the exclusion of any other possible combination of teaching represented by the combination of Uno, Aiache, Nishihara, Yasuda, Janda and Ohmura.

Therefore, claims 1, 3-5 and 14-16 are unobvious over Uno, Aiache, Nishihara, Yasuda, Janda and Ohmura because there was no teaching to select the claimed element of a monomer having a nitrogen atom in its side chain being (meth)acrylamide, no finite number of solutions when considering the references as a whole and no predictability of results.

B. "SULC" rejections

Claims 6, 7, 11 and 12 were rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Sulc et al. ("**Sulc**") in view of Aiache et al. ("**Aiche**"), Lee et al. (Material Science and Engineering C, 2002, 20:161-166 – "**Lee**"), Atkinson et al. (EP 0032443 – "**Atkinson**") and Kato et al. ("**Kato**").

The arguments made above with respect to consideration of the references as a whole also applies to the Sulc rejections. However, the Sulc rejections are even further removed from establishing obviousness because Sulc does not teach what is being asserted in the Office Action.

The Office Action acknowledges that Sulc never teaches the claimed ratio of the invention (the closest embodiment is 90.7% of Example 1 of Sulc), i.e. there was no direction to suggest that the anionic/cationic parameter was to be optimized; the only direction came from the necessity of the Office Action to account for this difference which would not have existed to one of ordinary skill in the art who does not have the applicants' claims before them as does the Examiner.

Furthermore, Sulc refers to cationic-anionic pairs which are employed in the polymerization of a *balanced charge polymer* of their invention is made up of substantially equimolar amounts of an ethylenically unsaturated cationic monomer and an ethylenically unsaturated anionic monomer (see col. 2, lines 51-59) in order to provide a hydrophilic contact lens exhibiting a significantly reduced tendency to accumulate proteinaceous materials, etc. upon its surface (see col. 2, lines 41-47).

Based on the disclosure of Sulc, at best one of ordinary skill would adjust the molar ratio of the anionic monomer to the cationic monomer to 1:1 in order to achieve the desired lack of debris retention on the lens surface. This is further borne out by the previous example of Sulc highlighted in the previous Office Action, i.e. Example 17 which had a ratio of 109%. Taking Examples 1 and 17 as representative teachings, one of ordinary skill in the art would be directed to anionic/cationic ratios which deviate less than 10% from 100% with the preferred direction being 100% (i.e. a 1:1 ratio), i.e. 90% is not encompassed nor is there any reason to experiment in that direction. Therefore, the claimed molar ratio of the anionic monomer to the cationic monomer is not obvious to one of ordinary skill over Sulc.

Aiache is only relied upon for a generic teaching of drug delivery from an ophthalmic lens and the inclusion of an anionic group containing drug and does not remedy the deficiencies of the Sulc reference.

As claims 11 and 12 are directly or indirectly dependent upon claim 6, the arguments presented above with respect to Sulc in view of Aiache would also be applicable to claims 11 and 12. The reason for modifying Sulc is even further removed for the element of claim 11 - "the copolymer contains the anionic monomer in a ratio of 40 to 80 mol. % to the cationic

monomer.” As noted above, Sulc is directed to “a polymer of essentially *balanced charge*” (see Background of the Invention (col. 1, lines 6-8 and Description of Preferred Embodiments (col. 2, lines 49-52))

The applicants’ previous response with respect to the inclusion of water-soluble azulene (claim 12) and the use of Kato was never adequately addressed as there was no factual basis for the opinions offered with regard to the teachings of Kato.

As with all cited references, the Kato reference must be considered as a whole with the teachings of Sulc and Aiache. One of ordinary skill in the art reading the Kato reference would clearly see that it refers to the formation of *liposomes for the treatment of dry eye*. The liposomes are unrelated to the contact lenses of the applicant’s claimed invention or Sulc and Aiache nor does Kato contain the polymers which are related to either the applicants’ claimed invention or that of Sulc and Aiache.

Moreover, Kato’s reference to sodium azulene sulfonate is within a list of *non-essential ingredients* cited by Kato (see col. 2, lines 6-33) and furthermore, these non-essential components are used with the liposome in the context of treating dry eye, i.e. for the rapid release of the non-essential component whereas Sulc does not teach a release rate for active substances at all.

In contrast, the active ingredient within the applicants’ claimed drug delivery ophthalmic lens achieves a much slower and controlled release rate of the active ingredient (see Example 7).

However, as Lee and Atkinson does not remedy the deficiencies of the combination of Sulc, Aiache and Kato, claims 6, 7, 11 and 12 are unobvious over the cited references for this reason alone.

In order to keep the issue alive for Appeal, the applicants note that Lee and Atkinson at best suggest the optimization of conditions in Sulc which would destroy the inventive characteristics of Sulc’s product, i.e. having a polymer of essentially balanced charge. It is well known that “[if the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

For any of the above reasons, claims 6, 7, 11 and 12 are unobvious over the combination of Sulc, Aiache, Lee, Atkinson and Kato.